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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,876	03/11/2004	Arthur E. Uber III	IN/02-002.PCT.US.C	4883

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,876	UBER ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-143* is/are pending in the application.

4a) Of the above claim(s) *42-139* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41 and 140-143* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-143 are pending in the application. Claims 42-139 are withdrawn from consideration.

Response to Arguments

1. Applicant's arguments filed 5/29/08 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-41 and 140-143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossling et al. (US 6,468,506B1) in view of Evans, III et al. (US 5,885,216) and further in view of Daum et al. (US 6,231,513) or Quay et al. (WO 96/40282) as stated in the office action mailed 11/5/07.

4. Applicant asserts that Rossling et al. fails to disclose a system for administering into a patient a medium in which the bubbles therein are created according to the demands of the medical procedure.

5. The instant claims 1-41 are drawn to a system and are therefore product-by-process limitations. Therefore the recitation of, "created according to the demands of a medical procedure" does not impart any patentability of the instant claims. Even though

product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113. Also there are no limitations recited in regards to the medical procedure and therefore the system of the combined disclosures encompasses the system of the instant claims.

6. Applicant asserts that Rossling et al. contains no teaching of a controller that controls operation of the system real time so that the bubbles created by the bubble generator according to the demands of the medical procedure to which the patient is subjected.

7. The instant claims 1-41 are drawn to a system and are therefore product-by-process limitations. Therefore the recitation of, "created according to the demands of a medical procedure" does not impart any patentability of the instant claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

8. In regards to the controller for controlling operation of the system real time, it would be obvious that one would skilled in the art that the controller for controlling operation of the system would occur at real time as the initiation of the system (bubble preparation) is accomplished by a person and/or computer system (which is activated by a person and/or automated).

9. Applicant asserts that Evans, III et al. teaches only the mixing of contrast to the desired concentration and delivery of same into the patient. Applicant asserts that Evans, III et al. teaches nothing about the generation of bubble-based media and control of same (real time or otherwise) according to the demands of the medical procedure to which the patient is subjected.

10. The reference of Evans, III et al. was not used to teach of the generation of bubble-based media but to teach of apparatus for the injection of a contrast medium/bubble-based media into a patient. Rossling et al. was used to teach apparatus for the production of gaseous microparticles. In combination, it would have been obvious to one skilled in the art to use the apparatus for the injection of a contrast medium/bubble-based media (Evans, III et al.) to inject the microparticles/contrast agents of Rossling et al. into a patient. Also, it would be predictable to one skilled in the art to inject the microparticles/contrast agents of Rossling et al. into a patient via the apparatus of Evans, III et al. since Rossling et al. teaches that the contrast agents meet the requirements for intravenous administration, have good compatibility without having an allergic potential and not to agglomerate in an aqueous medium (column 2, lines 26-33).

11. Applicant asserts that the process taught by Rossling et al. uses toxic solvent(s) to create the dried microparticles and thus requires their removal from the mixture before the dried microparticles can be obtained therefrom.

12. Rossling et al. teaches that the contrast agents meet the requirements for intravenous administration, have good compatibility without having an allergic potential and not to agglomerate in an aqueous medium (column 2, lines 26-33). Rossling et al. teaches the microparticles are quickly degraded in vivo, degradation products are toxicologically harmless, they circulate for a sufficiently long time in the blood circulation, etc. (column 4, lines 15-39). Rossling et al. also teaches that depending on the drying time, optionally a small amount of liquid (water or perfluoror compound) remains as vapor in the particles (column 2, lines 46-53) and therefore it would be obvious that the particles of Rossling et al. are used for medical procedures.

13. Applicant asserts that there is no suggestion whatsoever as to what point in the method of Evans, III et al. the dried microparticles of Rossling et al. would be added or how they would be processed by the combined system so that a bubble-based contrast agent safe for human use would be created.

14. Rossling et al. teaches that the contrast media for ultrasonic diagnosis that contain microparticles may be obtained by the dried microparticles being resuspended in a pharmaceutically acceptable suspension medium, such as water, p.i., aqueous solution of one or more inorganic salts, etc. (column 3, lines 50+; column 4, lines 1-12). The contrast medium apparatus of Evans, III et al. provides for continuous variation of the concentration of the contrast medium by the controller (column 3, lines 1-8).

Therefore the preparation and administration of the contrast medium generated from the resuspended microparticles would be obvious to one skilled in the art.

15. Applicant asserts that the size of the dried microparticles created by the method of Rossling et al. is entirely dependent on the size, shape and type of nozzle used in their manufacture. Therefore combining Rossling et al. and Evans, III et al. yields a contrast dilution system in which the bubbles could not be generated or controlled according to the demands of the medical procedure to which the patient is undergoing.

16. The instant claims 1-41 are drawn to a system and are therefore product-by-process limitations. Therefore the recitation of, "created according to the demands of a medical procedure" does not impart any patentability of the instant claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

17. Applicant asserts that Daum et al. pertains only to the creation of bubbles directly within a blood vessel by means of gas injected via a needle.

18. Daum et al. teaches that that the hollow tubular lumen includes a microbubble forming arrangement for forming bubbles when a gas is passed through the distal end of the hollow tube and that the invention provides for delivery of gaseous microbubbles (abstract; column 1, lines 54-55). Therefore the microbubble formation is prior to

injection at the microbubble forming arrangement. The microbubble forming arrangement can be a porous matrix having microholes or microchannels (column 2, lines 1-3).

19. Applicant asserts that Quay et al. creates bubble-based media as only through the use of "a hypobaric force on the solution" and in bulk volume and only in response to the lowering of pressure in the container in which the solution is stored.

20. The instant claims do not exclude lowering the pressure of the system and do include a pressurizing device. The reference of Quay et al. was used to teach of the enhancement in the production of gaseous microbubbles via the introduction of solid particles, which is a known technique in the art.

Conclusion

No claims are allowed at this time.

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618